

THE CLAIMS

What is claimed is:

- 5        1.    A method for treating gastroesophageal reflux  
disease, which comprises administering to a mammal in need of  
such treatment a therapeutically effective tissue bulking  
amount of biocompatible hydrophilic microparticles, said  
administration being into the lower esophageal sphincter or  
10 the diaphragm.
2.    The method of claim 1, wherein the microparticles  
are cationic.
3.    The method of claim 1, wherein the microparticles  
15 comprise a positive charge on their surface.
4.    The method of claim 1, wherein said mammal is a  
human.
- 20        5.    The method of claim 1, wherein the microparticles  
are pre-treated with, administered with, or coated with  
autologous cells.
6.    The method of claim 5, wherein the microparticles  
25 or cell coated microparticles are washed with serum or whole  
blood prior to administration.
7.    The method of claim 5, wherein the autologous cells  
are mucosal cells, muscle cells, fat cells, or combinations  
thereof.  
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8. The method of claim 1, wherein the microparticles are coated with or linked to at least one collagen or a derivative thereof, glucosaminoglycans, or a mixture thereof.

5 9. The method of claim 1, wherein the microparticles are administered in a sterile and pyrogen-free injectable solution.

10 10. The method of claim 1, wherein the microparticles are spherical.

10 11. The method of claim 10, wherein the microparticles comprise a hydrophilic copolymer which comprises in copolymerized form about 25 to about 99% by weight of neutral hydrophilic acrylic monomer, about 2 to about 50% by weight  
15 of one or more monomers having a cationic charge, and about 1 to about 30% by weight of a functionalized monomer.

20 12. The method of claim 10, wherein said microparticles have diameters ranging from about 10 $\mu$ m to about 1000 $\mu$ m.

13. The method of claim 1, wherein said administration is made via syringe, catheter, or combinations thereof.

25 14. The method of claim 1, wherein said microparticles comprise or are administered with one or more of a therapeutic agent, an anti-inflammatory agent, an angiogenesis inhibitor, a radio active element, and an antimitotic agent.

30 15. The method of claim 1, wherein the microparticles further comprise a cell adhesion promoter.

16. The method of claim 15, wherein said cell adhesion promoter is selected from the group consisting of fibronectin, laminin, chondronectin, entacin, epibolin, liver cell adhesion molecule, serum spreading factor, collagen, heparin sulfates, dermatan sulfates, chondroctin sulfates, glucosaminoglycans, and mixtures thereof.

17. A sterile injectable solution suitable for treating gastroesophageal reflux disease, which comprises:

- (a) biocompatible hydrophilic cationic microspheres, having a diameter of 10 to 1000  $\mu\text{m}$ , said microspheres comprising a neutral hydrophilic monomer, one or more cationic monomers, one or more functionalized monomers; and
- (b) autologous cells.

18. The solution of claim 17, wherein the microspheres further comprise a cell adhesion promoter.

19. A method for treating gastroesophageal reflux disease, which comprises:

- (a) preparing cationic microparticles which comprise biocompatible and hydrophilic polymers;
- (b) administering the resulting microparticles to a mammal by injection into walls of a sphincter located where the esophagus meets the stomach.

20. The method of claim 19, wherein the microparticles further comprise a cell adhesion promoter.